REMARKS

Claims 24, 27 and 28 have been rejected. No claims have been amended. No claims have been added or canceled.

Applicant has carefully studied the outstanding Office Action. The present Response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of this application are respectfully requested. No new matter has been added by any of the amendments to the specification. Applicant respectfully requests reconsideration and withdrawal of the Examiner's rejections in view of the foregoing amendments and following remarks.

CLAIM REJECTIONS – 35 U.S.C. §112

Claims 24, 27 and 28 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner states:

> The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
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> Claims 24 and 28 recite various numerical range limitations regarding the amounts of elements a) through c) which are not supported by the instant specification (i.e, the Examiner could not find support for the narrower ranges instantly claimed, nor did Applicants particular point to such support within the instant specification). In other words, the instant specification does not support the following numerical percentage ranges:
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> -a range from 0.001 to 2.0% of carboxymethylcellulose (i.e., the specification appears to only support a range from 0.01 to 10.0% of this element).
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> -a range from 5.0 to 20.0% of propylene glycol (i.e., the specification appears to only support a range from 0.001 to 50.0% of this element).
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> -a range from 0.1 to 1.0% of methylparaben (i.e., the specification appears to only support a range from 0.001 to 3.0% of this element).

Response

Ranges in a claim can be narrower than those disclosed in specification. In *Ralston Purina Co. v. Far-Mar-Co.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985), the Federal Circuit expressly rejected the notion "that ranges found in the applicant's claim language must correspond exactly to ranges disclosed in the parent." This is because neither the Patent Act nor the case law requires such detailed disclosure. *See In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1533 (Fed. Cir. 1992) ("[The applicant] does not have to describe exactly the subject matter claimed."); *Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1566 (Fed. Cir. 1991) ("ranges found in applicant's claims need not correspond exactly to those disclosed in [the specification]; issue is whether one skilled in the art could derive the claimed ranges from the [] disclosure."). Rather, the Patent Act and this court's case law require only sufficient description to show one of skill in the refining art that the inventor possessed the claimed invention at the time of filing. *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 1001 (Fed. Cir. 2000). To satisfy the written description requirement, the claimed invention need not be expressed *ipsis verbis* in the original specification. *In re Wertheim*, 541 F.2d 257, 262, 190 U.S.P.Q. 90, 96 (C.C.P.A. 1976). In *In re Wertheim*, the CCPA found that a claimed range of 35% to 60% based upon a written description disclosing a range of 25% to 60% having did meet the description requirement. *See also* MPEP 2163.05 III. Applicant's claimed ranges are within the ranges disclosed in the specification, like the range in *In re Wertheim*.

The Examiner understands that there is no support in the specification for claims 24, 27 and 28. Applicant emphasizes that on page 7, line 16 of the specification, it is disclosed that although the antioxidant activity of *Pariparoba* was known, it is not obvious to imagine which specific gel formulation serves as a vehicle for this drug in order to obtain a therapeutically effective gel composition. Furthermore, there are not specific studies about the performance of

active principle of this plant in the oxidative stress caused by ultraviolet radiation. Figure 3 shows the effectiveness of the proposed vehicle showing that 4-NC is present on (into) the skin. In the present application, it was demonstrated for the first time the activity *in vivo* of the extract in mice chronically exposed to ultraviolet radiation. Applicant respectfully requests that Examiner withdraw the rejection.

CLAIM REJECTIONS – 35 U.S.C. §103

Claims 24, 27 and 28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ropke et al. (Free Radical Biol. Med., Vol 33, Issue 2, Abstract #527, 15 July 2002) and Ropke et al. (Annals of the 14th National Cosmetology Congress of the Brazilian Cosmetology Assoc, 20000) – including entire English Translation of this document) in view of Wheeler (US 6,165,479) and, if necessary, the admitted state of the art. The Examiner states:

> The two cited Ropke et al. references each beneficially teach a topical gel compositions having strong therapeutic antioxidant activity which comprises an extract of *Pothomorphe umbellata*, whereby the gel compositions comprises 4-nerolidylcatechol (on the basis of the *Pothomorphe umbellata* extract). In addition, the second Ropke et al. reference (2000) discloses a topical compositions presented in a gel form (i.e., within diadermine – an oil/water emulsion) comprising an extract of *Pothomorphe umbellata*, whereby the topical compositions comprises 0.2%, 0.05, 0.1, 0.2, and 2% (p/p) of 4-nerolidylcatechol therein; and further that the dry extract contains 2.35% of 4-nerolidylcatechol therein (see, e.g., page 8 of English Translation) – thus, apparently within the instantly claimed ranges therein. The cited Ropke et al. references also teach topically applying the gel compositions to the skin of hairless mice (see Abstract # S527 of the first Ropke et al. reference; and entire English translation including pages 2-5, 7-9, 13-14, 16, and final paragraph on page 18 of the second Ropke et al. reference) – e.g., as a photoprotective agent for treating skin cancer and/or aging. Neither of the Ropke et al. references expressly teaches providing the skin therapeutic *Pothomorphe umbellate* extract within a skin gel composition containing carboxymethylcellulose, propylene glycol, and methylparaben, as instantly claimed.

> Wheeler beneficially teaches that carboxymethylcellulose, propylene glycol, and methylparaben are well known conventional ingredients within skin therapeutic compositions such as skin gels, including those containing an antioxidant therein (see entire reference including col 2, line 58 – col 4, line 67). Further, as readily admitted by Applicants, the instantly claimed dermocosmetic composition can be prepared in accordance with prior art methods for topical use – such as one containing carboxymethylcellulose, propylene glycol, and methylparaben (see, e.g., page 11, lines 1-5).
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> It would have been obvious to one ordinary skill in the art at the time the claimed invention was made to incorporate the *Pothomorphe umbellata* extract preparation having strong therapeutic antioxidant activity as taught by each of the Ropke et al. references into a conventional skin therapeutic formulation (e.g., as an effective antioxidant) – including a skin gel, containing the commonly-employed skin care ingredients caboxymethylcellulose, propylene glycol, and methylparaben therein based upon the beneficial teachings provided by Wheeler, as well as (if necessary) the admitted state of the prior art, with respect to their well known conventional use therein, as discussed above. Accordingly, the adjustment of this and other types of conventional working conditions (e.g., determining an appropriate amount range of such conventional ingredients therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.
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> Thus, the invention as a whole was clearly *prima facie* obvious over the references (and, if necessary, the admitted state of the art), especially in the absence of clear and convincing evidence to the contrary.

Response

Applicants believe that the two cited Ropke et al. references do not show the features as asserted by the Office Action. On page 3 of the Office Action, the Examiner considers the publications of Ropke et al. (2002) and Ropke et al. (2000) to disclose the topical use of a gel. In the Ropke et al (2002) reference, although the summary mentioned the use of gel, the components of said gel were not specified. Furthermore, as stated in the Response to Final Office Action filed on February 5, 2008, the Ropke et al (2002) reference should not be

considered prior art by the Examiner, since it was published by the inventors within the grace period of the present application (Ropke et al. (2002) was published by the inventors themselves, two months prior to the filing of the Brazilian priority application (PI0204130-8) which was filed on September 18th, 2002).

Also, the Ropke et al (2000) reference does not disclose a gel. There are four categories of semi-solid preparations disclosed: ointments, creams, gels or paste. Gels are semi-solid system consisting of suspensions of small inorganic particles or large organic molecules interpenetrate by a liquid, as is the formulation of the present application, while ointments are preparations for topical application, consisting of a single base, which may be dispersed solids or liquids, for example, Diadermine. Therefore, Applicant respectfully submits that Examiner made a conceptual error in such assumption. As known by a person with ordinary skill in the art, gels and Diadermine compositions are completely different and the incorporation of an active ingredient in these compounds results in completely different therapeutics effects.

A prima facie case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993). On page 4, paragraph 2 of the Office Action, the Examiner states that Wheeler et al. teaches that carboxymethylcellulose, propylene glycol, and methylparaben are well known conventional ingredients within skin therapeutic compositions. However, Applicant asserts that the present invention is not limited to a simple addition of an antioxidant to the composition, but a composition that presents photoprotective activity *in vivo*, wherein lies the non-obviousness of the invention.

Also, on page 4, paragraph 3, Applicant discloses that the present invention is not based on antioxidant activity, but on photoprotective activity (photodamage). It is not possible to say

that any substance that presents antioxidant activity is a photoprotector. Therefore, it would not be obvious to one of ordinary skill in the art to deduce this property. On page 7, line 16 of the specification of the present application, it was mentioned that although the antioxidant activity have been known (prior art), the absorption on skin was fundamental to the effect *in vivo,* which shows the protection of the skin against ultraviolet radiation. Consequently, the teachings of the prior art do not suggest the claimed subject matter to a person of ordinary skill in the art. In view of this, Applicant respectfully requests that Examiner withdraw the rejection.

Claims 24, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchiyama et al. (JP 2001122763 - full computer-assisted English translation enclosed) in view of Barros et al. (Ciencia e Cultura, 1996) and Desmarchelier et al. (Planta Med, 1997), and further in view of Wheeler (US 6,165,479) and, if necessary, the admitted state of the art.

> Uchimyama et al. beneficially teach a topical skin composition (e.g., in the form of a lotion, cream, etc.) comprising an extract of *Pothomorphe umbellata* (including an alcoholic extract such as an ethanolic or methanolic extract - please note, as evidenced by Barros et al. and Desmarchelier et al., such an alcoholic extract would inherently comprise the naturally occurring compound 4-nerolidylcatechol) as an active skin therapeutic ingredient therein (e.g., useful against skin aging caused by ultraviolet rays among other therapeutic effects), as well as topically applying such a composition to the skin. Uchimyama et al. also beneficially teach that the extract composition has antioxidant activity (i.e., oxygen-eliminating ability) - such as instantly disclosed (see entire English translation including paragraphs [0007] - [0016], [0021], [0028], [0034]-0035], [0037], and Tables).
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> The Barros et al. and Desmarchelier et al. references each beneficially teach a composition comprising an alcoholic (ethanolic - Barros et al; methanolic - Desmarchelier et al) extract of *Pothomorphe umbellata* - whereby the extracts demonstrate strong antioxidant activity (such as instantly disclosed) which contain the compound 4-nerolidylcatechol - apparently within the instantly claimed percentage range (as best understood) - therein (see entire documents including *Abstract and*

Materials and Methods).

None of the above references, including Uchimyama et al., expressly teach providing the skin therapeutic *Pothomorphe umbellata* extract within a skin gel composition - including one containing carboxymethylcellulose, propylene glycol, and methylparaben, as instantly claimed.

Wheeler beneficially teaches that carboxymethylcellulose, propylene glycol, and methylparaben are well known conventional ingredients within skin therapeutic compositions such as skin gels, including those containing an antioxidant therein (see entire reference including col 2, line 58 - col 4, line 67). Further, as readily admitted by Applicants, the instantly claimed dermocosmetic composition can be prepared in accordance with prior art methods for topical use - such as one containing carboxymethylcellulose, propylene glycol, and methylparaben (see, e.g., page 11, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate an alcoholic (e.g., ethanolic or methanolic) extract of Pothomorphe umbellata within the skin therapeutic composition (having antioxidant activity) as taught by Uchimyama et al, especially since Uchimyama et al. beneficially teaches that ethanolic and methanolic solvents are effective solvents to employ, and Barros et al. and Desmarchelier et al. beneficially teaches that such alcoholic solvents provide a Pothomorphe umbellata extract having strong antioxidant activity (in addition, it should again be noted that, as evidenced by Desmarchelier et al., such an alcoholic extract would inherently comprise the naturally-occurring compound 4-nerolidylcatechol therein). It would further have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate such a *Pothomorphe umbellata* extract into a conventional skin therapeutic formulation (e.g., as an effective antioxidant) - including a skin gel, containing the commonly-employed skin care ingredients carboxymethylcellulose, propylene glycol, and methylparaben therein based upon the beneficial teachings provided by Wheeler, as well as (if necessary) the admitted state of the prior art, with respect to their well known conventional use therein, as discussed above. Accordingly, the adjustment of this and other types of conventional working conditions (e.g., determining an appropriate amount range of such ingredients therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole was prima facie obvious over the references (and, if necessary, the admitted state of the art) especially in

the absence of clear and convincing evidence to the contrary.

Response

A prima facie case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993). Uchiyama et al refers to formulations with antioxidant activity and does not indicate the formulations which are in the form of gel. Barros et al, (1996) and Desmarchelier et al. teaches only a composition comprising an antioxidant activity. None of the references, including Uchimyama et al, expressly teach providing the skin with therapeutic *Polhomorphe umbellata* extract within a skin gel composition including photoprotective activity. The Wheeler reference does not show the photoprotective activity of these formulations containing carboxymethylcellulose, propylene glycol, and methylparaben. Consequently, the teachings of the prior art do not suggest the claimed subject matter to a person of ordinary skill in the art. In view of this, Applicant respectfully requests that Examiner withdraw the rejection.

Moreover, the therapeutic gel composition of the present application is not merely a matter of common selection and routine optimization which is well within the experience of a person with ordinary skill in the art. The composition of the present invention is a formulation in gel form containing the extract which creates the effects claimed in claim 28. Therefore, it is not obvious that mixing the *Pothomorphe umbel/ala* extract will induce the photoprotective activity.

All references cited as prior art refer only to the antioxidant activity and Wheeler et al. refers only to compositions for topical use that do not mention the effect claimed by present application, namely, photoprotective activity (photodamage). Together or separately, the

mentioned documents do not compromise the non-obviousness of the present invention. In view of this, Applicant respectfully requests that Examiner withdraw the rejection.

None of the references mentions the main subject-matter of the present application, which refers to the incorporation of the extract of *Pothomorphe* in a gel formulation, with the specified components and with photoprotective activity and other effects as claimed in claim 28. In order to obtain these effects, it is necessary permeate the skin, which was also an object of the present invention. The Examiner did not properly take into account these properties that characterize the invention.

Further, according to the Examiner, any antioxidant added to any formulation would produce the effect showed in claim 28. Applicant respectfully disagrees with Examiner. Not all photoprotectors are antioxidants. In most cases, the photoprotector acts as a barrier function and has no antioxidant activity. Also, not all antioxidants have photoprotective activity, and in equal intensity. One reason for this is that for performing the effect demonstrated in the present application, the active ingredient must permeate the skin which was only achieved in the present application (please refer to Figure 3 of the Specification). The present application was able to dissolve and stabilize the 4-Nerodliycathecol, a highly lipophilic molecule, in a totally hydrophilic gel formulation, while at the same time, delivering the active principle into the skin at an adequate rate in sufficient amounts, demonstrating the importance of an appropriate gel composition for an accurate penetration of the drug.

The Examiner says, in the page 6, paragraph 3, that "none of the references, including Uchimyama et al, expressly teach providing the skin therapeutic *Pothomorphe umbellata* extract within a skin gel composition - including one containing carboxymethylcellulose,

propylene glycol, and methylparaben, as instantly claimed." This statement seems to contradict Examiner's earlier statements.

Based on the above references, it would not have been obvious to imagine an extract of *Pothomorphe* in a gel formulation with the specified components. Furthermore, it would not be possible to foresee that such gel composition with *Pothomorphe umbellata* extract had photoprotective activity. Consequently, Applicant respectfully requests that Examiner withdraw the rejection.

CONCLUSION

In light of the amendments and the arguments made by Applicants above, as well as the evidence previously submitted, Applicants submit that all existing, examined claims are now in a condition for allowance. Applicants respectfully request that Examiner withdraw all restrictions and rejections with regard to the above-referenced claims in reliance on one or more of the grounds submitted by Applicants.

If there are any outstanding issues that the Examiner feels may be resolved by way of telephone conference, the Examiner is invited to call David Carstens or Celina Diaz at the below-listed telephone number if in the opinion of the examiner such a telephone conference would expedite or aid the prosecution and examination of this application.

The Commissioner is hereby authorized to charge any payments that may be due or credit any overpayments to CARSTENS & CAHOON, LLP Deposit Account 50-0392.

Respectfully submitted,

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By: _____

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